

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 RSC-01 AGR-10 OES-05 /033 R

DRAFTED BY HEW/FOA:WJKUSTRKA:JS

APPROVED BY ARA-LA/CEN:DAVID LAZAR

TA/AGR:KONNERUP

ARA/CEN:PHWACKERBARTH

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R 102315Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY TEGUCIGALPA

INFO AMEMBASSY GUATEMALA

UNCLAS STATE 006670

GUATEMALA FOR AGATT

E.O. 11652: N/A

TAGS: EAGR, SNAR, HO

SUBJECT: PARBENDAZOL CATTLE VERMIFUGE

REF: STATE 267535

1. THE FOOD AND DRUG ADMINISTRATION HAS INFORMED US THAT AN ERROR WAS MADE IN PREPARING STATE 267535. THIS REPLY GAVE INFORMATION APPLICABLE TO THE USE OF THIABENDAZOLE (CHEMICAL NAME, 2-(4-THIAZOLYL)-BENZIMIDAZOLE) IN CATTLE. TEGUCIGALPA 5125 REQUESTED INFORMATION ON THE STATUS OF PARBENDAZOLE (METHYL-5-BUTYL-2-BENZIMIDAZOLECARBAMATE) FOR USE IN CATTLE AS AN ANTHELMINTIC AGAINST VARIOUS SPECIES OF GASTROINTESTINAL NEMATODES. THIS DRUG IS NOT REPEAT NOT APPROVED FOR USE IN FOOD-PRODUCING ANIMALS IN THE U.S. AND ITS EXPORTATION FROM THE U.S. WOULD BE IN VIOLATION OF SECTION 801(D) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT IN THAT IT IS A NEW ANIMAL DRUG WHICH IS UNSAFE WITHIN THE MEANING OF SECTION 512 OF THE ACT.

2. A FOOD ADDITIVE PETITION PROPOSING THE ISSUANCE OF A
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FOOD ADDITIVE REGULATION (21 CFR 121) TO PROVIDE FOR THE

SAFE USE OF PARBENDAZOLE, ADMINISTERED AS AN ORAL DRENCH WAS PUBLISHED IN THE FEDERAL REGISTER OCTOBER 30, 1968 BY SMITH, KLINE AND FRENCH, PHILADELPHIA, PA. THE FIRM ALSO PROPOSED TO MARKET THE DRUG IN PELLET FORM AND AS A FEED PREMIX.

3. ALTHOUGH THERE EXISTS A GREAT AMOUNT OF DATA EVIDENCING THE EFFECTIVENESS OF THE DRUG, TOXICOLOGY STUDIES HAVE DEMONSTRATED TERATOGENIC EFFECTS AND A POSSIBLE EMBRYOTOXIC EFFECT IN RATS AT LEVELS AS LOW AS 0.5 MILLI-GRAMS/KILOGRAM OF BODY WEIGHT.

4. IN VIEW OF THE UNRESOLVED QUESTION OF SAFETY TO THE ANIMALS AND THE UNKNOWN EFFECTS OF TISSUE RESIDUES IN HUMANS, THE PETITIONS FOR THE USE OF THE DRUG WERE WITHDRAWN IN JUNE AND JULY, 1968. THE FDA WOULD APPRECIATE ANY INFORMATION REGARDING POSSIBLE SHIPMENTS OF THE DRUG TO HONDURAS WHICH MAY BE ORIGINATING IN THE U.S. KISSINGER

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Message Attributes

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Disposition Approved on Date:
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Disposition Event:
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